## REMARKS/ARGUMENTS

The non-final Office Action mailed August 9, 2006 has been carefully reviewed and these remarks are responsive to that office action. Reconsideration and allowance of this application are respectfully requested. Claims 7-9 and 12-20 have been withdrawn without prejudice as being drawn to a non-elected species and the right to file a divisional application is expressly reserved as to the subject matter of these claims in the event the claims are not later added back to the present application.

It is respectfully submitted that the above amendments render moot the objection to claims 1-6, 10 and 11.

The claims were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 has been amended via non-narrowing amendments to identify *S.trifoliatus* as *Sapindus (S.)trifoliatus* and to specify the nature of the extract.

Claims 1-16, 10 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al. (CA2409051A1). This rejection is respectively traversed.

The claims of the present application are styled in "consisting essentially of" form. As indicated in MPEP section 2111.03, this term is intended to limit the scope of the claims to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. *See In re Herz*, 537 F.2d 549, 551-552, 1990 U.S.P.Q. 461, 463 (C.C.P.A. 1976). In the present case, it is undisputed that the Gupta reference discloses a composition that includes *Sapindus trifoliatus* and *Emblica officinalis*. As demonstrated by the data submitted herewith in the Declaration of Sudershan K. Arora, the presence of the *Emblica officinalis* in the composition disclosed by Gupta is indeed sufficient to destroy the basic novel characteristics of the claimed invention. Specifically, the presence of *Emblica officinalis* significantly affects receptor binding properties of a composition that includes *Sapindus trifoliatus*. Gupta therefore not only fails to disclose the present invention, Gupta teaches directly away from the present invention.



Banner & Witcoff, Ltd
10 S. Wacker Drive, Suite 3000
Chicago, IL 60606
(312) 463-5000

As specified by claim 1, the claimed composition possesses affinity for at least one receptor selected from the group consisting of Gamma-Amino Butyric Acid (GABA)-A agonist site, Glutamate-alpha-**a**mino-3-hydroxy-5-**m**ethyl-4-isoxazole**p**ropionic **a**cid (AMPA) site, Glutamate-Kainate site, Glutamate-*N*-methyl-D-aspartic acid (NMDA) agonistic site, Glutamate-*N*-methyl-D-aspartic acid (NMDA) glycine (strychnine insensitive) site and Sodium channel (site 2). As set forth in Exhibit 1 to the enclosed Declaration of Dr. Arora, a criterion of 50% inhibition or greater is used to qualify a compound as being active in binding experiments.

Table 1 of the present application is excerpted below:

**Table 1:**

| **S.No.** | **Receptor** | **Percent inhibition with *Sapindus trifoliatus*** | |
|---|---|---|---|
| | | **2.5 µg/ml** | **250 µg/ml** |
| 1 | GABA A, agonist Site | 50.92 | 102.40 |
| 2 | Glutamate AMPA Site | 5.43 | 87.36 |
| 3 | Glutamate Kainate Site | -15.70 | 87.29 |
| 4 | Glutamate NMDA agonist Site | 7.27 | 98.14 |
| 5 | Glutamate NMDA glycine (Strychnine insensitive) site | 14.50 | 85.33 |
| 6 | GABA chloride TBOB | -5.12 | 85.03 |
| 7 | Glutamate chloride | -2.72 | 89.49 |
| 8 | Sodium site-2 | 19.98 | 69.54 |

Note that inhibition is above 50% for all of the indicated receptor sites at 250 µg/ml.

In contrast, receptor binding affinity with the anti-migraine formula mentioned in the Gupta patent is reported in the Arora Declaration. Table 3 from that Declaration is reproduced hereinbelow:

**Table 3: Receptor Binding affinity with the antimigraine formulation mentioned in Gupta et al patent.**

| S.No. | Receptor | Percent inhibition (Gupta et al composition) | |
|---|---|---|---|
| | | **2.5 µg/ml** | **250 µg/ml** |
| 1 | GABA A, Agonist Site | 19.21 | **95.95** |
| 2 | Glutamate, AMPA Site | -0.89 | 41.69 |
| 3 | Glutamate, kainate Site | -1.16 | 25.68 |
| 4 | Glutamate, NMDA agonist Site | 15.26 | **66.02** |
| 5 | Glutamate, NMDA glycine (Strychnine insensitive) site | 4.03 | 42.60 |
| 6 | GABA chloride,TBOB | -14.60 | -3.77 |
| 7 | Glutamate chloride | 1.95 | **84.35** |
| 8 | Sodium site 2 | 13.37 | 3.30 |

The differences in the foregoing data are striking. At 250 µg/ml, the composition of the invention exhibited greater than 50% inhibition for all of the referenced binding sites. In sharp contrast, the Gupta composition met this criterion only for three of the eight sites, and of those, binding affinity was reduced relative to the inventive composition.

From the above data, it is beyond dispute that the presence of *Emblica officinalis* does indeed affect the basic and novel characteristics of a composition made with *Sapindus trifoliatus* extract. It is noted further that the data in the Arora Declaration demonstrates that hederagenin in the Gupta composition originates from the *Sapindus trifoliatus*, and its presence is not due to *Emblica officinalis*. Gupta thus further teaches away from the presently claimed invention.

The Arora Declaration also contains toxicology data and a second HPLC analysis. The second HPLC analysis demonstrates that the amount of hederagenin in one of the formulations of the invention is significantly and unexpectedly higher than that of the cited art. The toxicology data demonstrates that the tested compound of the invention did not exhibit nasal irritation, and hence is useful for nasal application.



Banner & Witcoff, Ltd
10 S. Wacker Drive, Suite 3000
Chicago, IL 60606
(312) 463-5000

The Examiner states in the Office Action that "using a desired form of an extract" and "adjusting the pH of a solution" are "deemed merely a matter of judicious selection and routine optimization." Applicants respectfully disagree with the Examiner's comments, and submit that the Examiner's analysis is off the mark. The claims of the present application, styled in "consisting essentially of" form, have been drawn to exclude the *Emblica officinalis* extract that is specifically mandated by the Gupta reference. Based on the data of record, all claims of the present application are allowable.

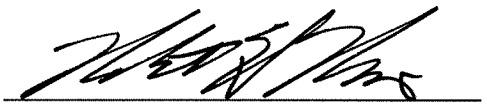
Applicants continue to traverse the restriction requirement. It is submitted that the restriction requirement should be withdrawn, especially in light of the foregoing. Unity of invention is found in the subject application.

**Conclusion**

All rejections having been addressed, applicants respectfully submit that this application is in condition for allowance.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: June 29, 2007 By: 

Robert H. Resis
Registration No. 32,168
BANNER & WITCOFF, LTD.
10 S. Wacker Dr., Suite 3000
Chicago, IL 60606-7407
Tel: (312) 463-5000
Fax: (312) 463-5001